

### **Remarks**

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

In item 1, the specification was objected to because the “status of the parent application needs to be updated on page 1 of the specification.” To remedy this informality, the specification has been amended to list the patent number for the parent application.

As will be discussed in greater detail below, claims 1-12 have been (or were previously) canceled without prejudice. No claims have been amended, and claims 21-24 have been added. Consequently, claims 13-24 are currently pending and under consideration. As should be appreciated, new claims 21 and 24 are supported by FIGS. 7 and 8 as well as the description of these figures that begins on page 6. In addition to the reasons discussed below for independent claim 19, it should be appreciated that claims 22 and 23 are supported by the originally filed claims, in particular claims 14 and 17.

As a housekeeping matter, the applicants believe that there might be some confusion as to which claims are pending in the present application. To help clarify the record in this regard, some background information concerning this case as well as its parent case has been provided below. Initially, it should be noted that in the July 5, 2000 Office Action for the parent case (now U.S. Patent No. 6,271,045) the claims were restricted in the following manner.

Group I- Claims 1-12, drawn to a device and method, classified in class 422, subclass 56.

Group II- Claims 13-18, drawn to a method of making a test strip, classified in class 427, subclass 2.13.

In the July 20, 2000 Response, claims 1-12 were canceled without prejudice and claims 19-24 were added. Subsequent to the July 20<sup>th</sup> response, a second restriction requirement was issued on October 11, 2000 in which the claims were restricted in the following manner.

Group I- Claims 13-18, drawn to a method of making a test strip, classified in class 427, subclass 2.13.

Group II- Claims 19-24, drawn to a test strip and method of testing, classified in class 436, subclass 514.

In the October 17, 2000 response to the second restriction requirement, the Group II set of claims, claims 19-24, were elected for prosecution and the Group I claims, claims 13-18, were withdrawn from consideration.

The present divisional application was filed in order to pursue the subject matter of claims 13-18, which were not elected in the parent case. The divisional application, as filed, included claims 1-18, and in the "Request For Filing Continuation/Divisional Application Under 37 C.F.R. §1.53(b)" that was filed along with the application, the applicants' previous representative requested that claims 1-12

be canceled. For the Examiner's convenience, a copy of this request has been enclosed. It is believed that the filing receipt confirmed the cancellation of claims 1-12 by noting that the application as filed contained one (1) independent claim and six (6) dependent claims, which seems to correspond to claims 13-18. On August 27, 2001, a Preliminary Amendment was filed in which claims 19 and 20 were added, and in the remarks, it was noted that "claims 13-20 are pending." However, in the present Office Action (September 3, 2003), claims 1-20 were indicated as pending, and claims 1-12 were rejected on various grounds, including obviousness-type double patenting. To eliminate any confusion and to obviate the obviousness-type double patenting rejection, claims 1-12 have been canceled without prejudice in the present response. It is believed that currently pending claims 13-20 are commensurate with the restriction requirement, and therefore, the labeling of the present application as a "divisional" application is proper.

The Applicants wish to thank the Examiner for allowing claims 13-18 in item 6 of the Office Action.

In item 2 of the Office Action, independent claim 19 was "rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, it was alleged that "[t]here is no disclosure of just a 'support member with a capillary' as recited in new claim 19" and that "[t]his language is broader than what is disclosed in the specification or shown in the

drawings.” It is well-settled law that the Patent Office has the initial burden of showing that a claim fails to satisfy the written description requirement. *See*, Manual of Patent Examining Procedures 8<sup>th</sup> Edition (MPEP) §2163.04. In traversal, the applicants submit that the Patent Office has failed to meet this burden by failing to show that claim 19 as well as its dependent claims do not satisfy the written description requirement.

One purpose of the written description requirement is to assure that the inventors were in possession of the invention being claimed at the time the application was filed. “To fulfill the written description requirement, the patent specification must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed.” *Cordis Corp. v. Medtronic AVE Inc.*, 67 USPQ2d 1876, 1885 (Fed. Cir. 2003). However, the disclosure as originally filed does not have to provide in *haec verba* or exact language support for the claimed subject matter at issue. *See, Id.* and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895 (Fed. Cir. 1996). Rather, as noted in §2163 of the MPEP, “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.” (emphasis added). Only under particular circumstances, does the removal of a limitation (i.e., broadening of a claim) raise an issue as to whether claims satisfy the written description requirement.

§2163.05 MPEP (citing, *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45

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USPQ2d 1498 (Fed. Cir. 1998)). With respect to broadly claimed inventions, “[a] specification may, within the meaning of 35 U.S.C. §112 para. 1, contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses.” *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709 (Fed. Cir. 1988). In clarifying the ruling of *Gentry*, the Federal Circuit has stated that it “did not announce a new ‘essential element’ test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.” *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317, 1323, 62 USPQ2d 1846 (Fed. Cir. 2002). “Rather, in *Gentry*, we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.” *Id.* (emphasis added).

It should be appreciated that after reviewing the specification and drawings that *Gentry* does not apply in this case because the present application does not clearly indicate that the invention is of a narrower scope than is claimed in claim 19. Initially, it should be noted that the invention recited in claim 19 concerns a method of making a strip, which is generally mechanical in nature, and therefore, highly predictable. In item 2 of the Office Action, it was asserted that the “originally filed claims require the capillary tube to be on one side of the support member” and “[t]here is no support for any other orientation of the capillary tube on the support member.” Nowhere does the specification indicate that the capillary tube must necessarily be oriented in such a manner, but rather, it is submitted that one of ordinary skill in the art would easily

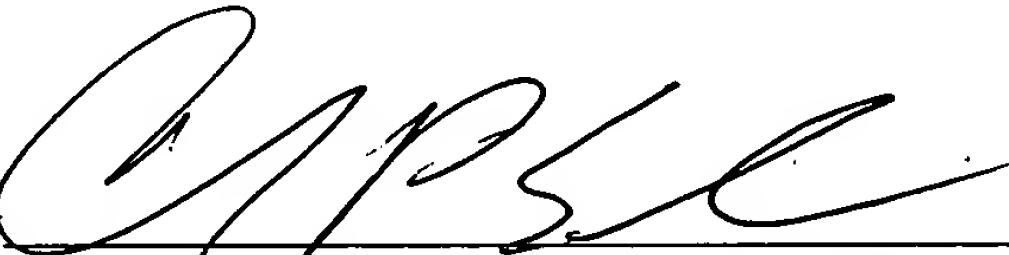
recognize, due to the predictable nature of this field, that the capillary tube could be oriented in other manners. Contrary to the Office Action, the specification, as originally filed, clearly supports a broader description of the orientation of the capillary tube. For example, the Summary of the Invention section describes an apparatus according to one embodiment (among others) that “comprises of a hydrophilic capillary tube in communication with a hydrophilic capillary wicking or spreading material which is in communication with an absorbent reagent membrane” (page 6, lines 10-19, specifically, lines 15-17). As should be appreciated, the description of this particular embodiment does not limit the relative position of the capillary tube in the manner as asserted in the Office Action. Likewise, at page 6, line 21 to page 7, line 4, another embodiment is not described in terms of a specific orientation of the capillary tube relative to the support member. These are just a few examples that show where the specification supports claims 19-20. After reading the above mentioned passages as well as the rest of the patent application, one of ordinary skill in the art would easily appreciate that the inventors had in their possession at the time of filing the inventions recited in independent claim 19 and its dependent claims. For this and other reasons, it is submitted that independent claim 19 and its dependent claims are supported by the originally filed application, and it is respectfully requested that the rejection of claims 19-20 in item 2 be withdrawn.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office

Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the applicants' undersigned representative by telephone to resolve such issues.

Respectfully Submitted,

By 

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